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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,651	10/31/2003	Kazuomi Kario	163852019900	8483

25227 7590 02/25/2005

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/697,651	Applicant(s) KARIO ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 8, 9, 15, 18, and 24 are objected to because of the following informalities:

on line 1 of claim 8, "claims 1" should be replaced with "claim 1";

on line 3 of claim 9, "at least one of primary parameter axes" should be replaced with "at least one of a plurality of primary parameter axes";

on line 5 of claim 15 "the cardiovascular disease" should be replaced with "a cardiovascular disease";

on line 6 of claim 15, "the actual values" should be replaced with "actual values";

on line 3 of claim 18, "the intra-group" should be replaced with "intra-group";

on line 3 of claim 24, "at least one of" should be replaced with "at least one of a plurality of". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 16-30 are directed towards a computer program, wherein computer programs *per se* are considered non-statutory subject matter and cannot be claimed. See MPEP §2106 IV B 1(a). However, a claim to a tangible computer readable medium encoded with a computer program is statutory subject matter because it is a computer element that defines structural and functional interrelationships between the computer program and other components of a computer

that permit the computer program's functionality to be realized. Therefore, the applicants may overcome this rejection by replacing

the preamble (lines 1-2) of claim 16 with, "A cardiovascular disease risk analyzing program encoded on a computer readable medium, the program comprising a set of instructions for performing the following:"

"16 further comprising" on line 3 of claim 17 with "16, the instructions further comprising"; and

"further comprising" on lines 2-3 of each of claims 22 and 23, and on line 3 of each of claims 24-27 and 30 with "the instructions further comprising".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of claims 1 and 16, particularly with regard to the evaluating quantity calculating unit, is wholly unclear, making it difficult to discern the scope of the claim. Based on the claim language and information from the instant specification, the applicants appear to be claiming a blood pressure monitor comprising a blood pressure data storage unit and an evaluating quantity unit. The storage unit is for storing blood pressure data groups, wherein each data group corresponds to a measuring condition and includes at least one blood pressure data measured under that measuring

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condition. The evaluating quantity calculating unit calculates an evaluating quantity based on a relationship between blood pressure data in a first one of the blood pressure groups and blood pressure data in a second one of the blood pressure groups, the data in the first blood pressure group being measured under a different measuring condition than the data in the second blood pressure measuring group. If this interpretation of claim 1 is the intent of the applicants, the applicants should replace " between blood pressure data in the blood pressure data groups and the blood pressure data in another blood pressure data group with different measuring conditions" on lines 6-8 of claim 1 with "between blood pressure data in a first one of the blood pressure data groups and blood pressure data in second one of the blood pressure data groups having different measuring conditions than the first blood pressure data group", and claim 16 should be amended similarly. If an altogether different meaning is intended by the claim language of claims 1 and 16, the applicants are advised to reword each claim to clearly and definitely reflect that meaning. For the purposes of this examination only, the examiner is interpreting claim 1 as described above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 7, 8, 16, 17, 19, 20, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,699,195 to Nakazawa et al.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Nakazawa discloses a blood pressure monitor, comprising a blood pressure data storage unit for storing blood pressure data groups, each of which includes, per measuring condition, at least one blood pressure data measured under one measuring condition (col. 10, lines 14-31; col. 12, line 65-col. 13, line 36; col. 16, lines 28-62 of Nakazawa). An evaluating quantity calculating unit calculates an evaluating quantity based on an interrelation between the blood pressure data in the blood pressure data groups and the blood pressure data in another blood pressure data groups with different measuring conditions (fig. 10; col. 16, lines 28-62; col. 17 lines 6-42 of Nakazawa).

Regarding claims 2, 5, 7, 17, 20, and 22 an intra-group average calculating unit calculates intra-group averages of the blood pressure data in the blood pressure data groups for the blood pressure data groups with different measuring conditions (col. 16, line 39-26 of Nakazawa). With further regard to claims 5 and 20, the measuring conditions are a plurality of specified time zones (col. 13, lines 26-30; col. 16, lines 28-31 and lines 43-48; col. 17, lines 6-14 of Nakazawa). With further regard to claims 7 and

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22, the monitor comprises a clock unit 26 for outputting time information, wherein the blood pressure data storage unit discriminates the measuring conditions for each blood pressure data based on the time information output from the clock unit 26 and stores the blood pressured data according to measuring conditions (col. 13, lines 26-30; col. 13, line 65-col. 14, line 9 of Nakazawa).

Regarding claims 4 and 19, the evaluating quantity is related with a degree of a risk of cardiovascular diseases (col. 16, lines 33-38 of Nakazawa).

Regarding claims 8 and 23, an input unit is included through which a user inputs the measuring conditions and the blood pressure storage unit stores the blood pressure data based on the measuring conditions input from the input unit (col. 11, lines 54-col. 12, line 2; col. 12, lines 42-56; col. 13, lines 26-36 of Nakazawa).

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,355,000 to Ogura. Ogura discloses a blood pressure monitor comprising a blood pressure data storage unit (col. 6, lines 1-12 of Ogura) and an evaluating quantity calculating unit 64 (fig. 1 of Ogura). The evaluating quantity calculating unit calculates an evaluating quantity (AAI) based on an interrelation between blood pressure data in a first blood pressure data group and blood pressure data in a second blood pressure data group (col. 8, line 63-col. 9, line 23; col. 10, lines 41-65 of Ogura), the different groups at least including a blood pressure group having blood pressure data measured from the right ankle and blood pressure group having blood pressure data measured from the right arm.

As to the language “for storing blood pressure data groups each of which includes at least one blood pressure data measured under one measuring condition per measuring condition”, the applicants should note that this is merely “intended use” language that cannot be relied upon to define over Ogura, since Ogura discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. The storage unit of Ogura is certainly capable of storing the data groups as described in claim 1.

Regarding claim 4, the evaluating quantity (AAI) is related to a degree of risk of cardiovascular disease (col. 1, lines 16-34 of Ogura).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakazawa as applied to claims 1, 2, 4, 5, 7, 8, 16, 17, 19, 20, and 23 above. Nakazawa discloses that the plurality of time zones includes a first time zone directly before the user's bedtime (col. 13, lines 32-34 of Nakazawa) and a second time zone just after the user awakens (col. 14, lines 13-16 of Nakazawa). Nakazawa fails to specify that these time zones encompass a range of time between two hours before bedtime to two hours after bedtime and between two hours before awakening and two hours after awakening, respectively. However, the applicants have not disclosed that the specific time range

provided solves any stated problem or is for any particular purpose. Moreover, it appears that the device and method would work equally well using any time range encompassing a time just before going to bed and just after awakening. Accordingly, the use of a first time zone starting from two hours before bedtime and ending about two hours after bedtime and a second time zone starting about two hours before awakening and ending about two hours after awakening is deemed to be a design choice which fails to patentably distinguish over Nakazawa.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned

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by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Allowable Subject Matter

Claims 3, 9-15, 18, and 24-30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101 and 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 3, 15, 18, and 30 the prior art of record fails to teach or fairly suggest a blood pressure monitor or a computer program embodied on a computer readable medium wherein the evaluating quantity is based on an average value and a different value of the intra-group averages in the blood pressure data groups, in combination with all of the other limitations of the claim.

Regarding claims 9-14 and 24-29, the prior art of record fails to teach or fairly suggest a blood pressure monitor comprising a diagnostic unit or a computer program embodied on a computer readable medium comprising instructions for providing at least one threshold value on at least one of a plurality of primary parameter axes obtained as an intra-group averages of a plurality of blood pressure data groups with the different measuring conditions or average values and different values of the intra-group averages, defining a plurality of primary parameter areas, which are prescribed by the threshold values, in a primary parameter multi-dimensional area composed of the

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primary parameter axes, and determining or displaying which area of the primary parameter areas where actual values of primary parameters obtained based on the measured blood pressure data are present, so as to make a diagnosis based on the blood pressure data, in combination with all of the other limitations of the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,808,497 to Ogura et al.

US Patent No. 5,398,696 to Wiley


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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